

REMARKS

The limitations of claims 2, 3 and 16 have been incorporated into the main claim. The present invention relates to the treatment of cancer which focuses on reducing the mortality associated with Graft-v-Host Disease (GVHD), a condition that is caused by allogeneic hematopoietic cell transplant therapy, which is a primary treatment of blood-borne cancers.

Claims 1 – 18 stand rejected under 35 USC 112, first paragraph, on grounds that the claims are not enabled by the specification.

As now presented, the claims are limited to the use of beclomethasone dipropionate given in at least two dosage forms. The ability of this approach to reduce mortality in cancer patients has been shown in a clinical trial submitted to submitted to the U.S. Food and Drug Administration in support of a New Drug Application (NDA) for orBec® ORAL BECLOMETHASONE DIPROPIONATE TABLETS. A description of the study and its conclusions are submitted herewith in an executed Rule 132 Declaration by Dr. Robert N. Brey, Chief Scientific Officer of DOR Biopharma, Inc., which owns assignee Enteron Pharmaceuticals, Inc.

This study showed that patients treated with oral BDP, 2 mg four times daily for 50 days, have an improved outcome compared to patients treated with the same prednisone induction plus placebo, as measured by proportion of treatment failures at various time points, time to treatment failure to study day 80, as well as *survival* at transplant day 200. These improvements in outcome are achieved without an increase in clinically significant toxicity, yielding a favorable risk to benefit ratio.

CONCLUSION

Applicants submit that the case is now in condition for allowance. Early notification of such action is earnestly solicited.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,



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